REMARKS / ARGUMENTS

Claims 1-3, 6 and 8-12 remain pending in this application. No claims have been canceled or added.

Request for Acknowledgment of Priority

Applicants request that the Examiner acknowledge receipt of the certified priority documents at the National Stage. The Notification of Missing Requirements mailed October 29, 2001, indicates that the document has been received by the Patent Office. Applicants previously have requested acknowledgment of priority on three occasions, but so far have not received such an acknowledgment from the Examiner.

35 U.S.C. §112

Claims 1-3, 6 and 8-12 again stand rejected under 35 U.S.C. §112, second paragraph, as being identical for the reasons set forth on page 2 of the Action. The reasons are identified to the reason set forth in the last Office Action of September 2, 2005. In the amendment filed on May 16, 2006, Applicant's explained in detail the meaning of various terms questioned by the Examiner. The Examiner, however, did not comment on the explanations applicants submitted.

With respect to the Examiner's rejections under this section, Applicants again contend that one of ordinary skill in the art would easily understand the meaning of the terms used in the claims and that the claims set forth exact steps easily followed by one having ordinary skill in the art. However, in order to further prosecution and to assist the Examiner, Applicants provide the following comments.

An "analysis parameter" is an analysis condition and includes information such as the amount of a dispensed sample, reagents used for analysis, the amount of reagent used for analysis, a wavelength of absorbance under measurement, a type of reaction process, and a method of calculating a concentration, a standard sample, and a known concentration for use in calibration, etc. Analysis parameters are disclosed from page 1, line 16 to page 2, line 11, for example.

The information relating to reagents differs from one another, depending on the reagent makers, even for reagents used for analyzing the same testing item. In addition, even with reagents manufactured by the same reagent maker, the contents of analysis parameters may result in different information for different manufacturing lots. Thus, analysis parameters to be set must be always the latest analysis parameters related to reagents set in the automatically analyzing apparatus.

An accuracy management sample is one which has a known concentration. The status of an apparatus can be understood by measuring the accuracy management sample repeatedly in a predetermined interval. If the apparatus is normal, the same test results are obtained. If the apparatus is not normal, the test

results are different. Thus, "accuracy management" is the measuring of the accuracy management sample repeatedly and checking the status of the apparatus.

Generally speaking, accuracy management is used to manage a single apparatus. According to the present invention, accuracy management is used to manage different analysis apparatuses in different facilities. As such, it is possible that different test results may be obtained when plural apparatuses which are the same model of the same manufacturer and use the same reagent are used for the same patient. In an extreme situation, a patient could be judged to be normal in one hospital but judged to be abnormal in another hospital. To avoid this problem, the same accuracy management samples are analyzed using the same reagent in different facilities and a distribution of the test results is evaluated.

A "standard value" is a value that is standard in the case that the same accuracy samples are measured.

A "deviation calculation" is done for calculating a deviation of a measured value in a different facility for the same accuracy management sample from the standard value. Based on this deviation, a rating of the test result of the apparatus in the facility is evaluated. According to the present invention, this evaluation can be done in a service center using communication lines. See the specification at page 20, line 20 to page 23, line 12.

Once again, Applicants contend that the terms used in the claims are terms that would be easily understood by one of ordinary skill in the art. Furthermore, when the claims are read in light of the specification, their meaning can easily be ascertained.

35 U.S.C. §102

Claims 1-3, 6 and 8-12 again stand rejected under 35 U.S.C. §102(b) as being anticipated by JP 5-288756 or JP 4-128657. Claims 1-3 and 6-12 stand rejected under 35 U.S.C. §102(e) as being anticipated by Fritchie et al (U.S. Patent No. 6,022,746).These rejections are traversed as follows.

Viewed in light of the explaination of terms set forth above, claim 1 clearly defines exact steps which are easily followed by one having ordinary skill in the art.

Thus, claim 1 defines an analysis information management method using a service center having a data base connected to a plurality of automatic analyzing apparatuses used in a plurality of facilities through communication lines for storing analysis parameters related to a plurality of reagents for use in the plurality of automatic analyzing apparatus' used in the plurality of facilities.

Claim 1 clearly defines the method as comprising the definite steps of;

(1) transferring analysis parameters for a testing item to be analyzed using a reagent to one automatic analyzing apparatus of the plurality of automatic analyzing apparatus' through the communication line in response to a request from the one automatic analyzing apparatus.

(2) responsive to a request from the one automatic analyzing apparatus, the service center creates a list of reagents available in the one automatic analyzing apparatus from information on reagents stored in the database and supplies the one automatic analyzing apparatus with the list through the communication line.

(3) responsive to a selection of an association reagent from the list made by user of the one automatic analyzing apparatus, the service center transfers analysis parameters for a testing item to be analyzed using the selective reagent to the one automatic analyzing apparatus through the communication line.

(4) the service center classifies and stores information on analyses such as results of calibrations measured by the automatic analyzing apparatuses, results of analyses on accuracy management samples, reagents used in analyses, and analysis parameters for each facility or for each automatic analyzing apparatus and calculates, based on the stored information on the results of the analyses, a standard value for results of analyses on

accuracy management samples using the same reagents in all automatic analyzing apparatuses in all facilities administered by the service center, so that when a certain automatic analyzing apparatus administered by the service center has newly analyzed an accuracy management sample, the service center calculates a deviation between the result of analysis and the standard value for evaluation to verify that analysis parameters used in the analysis are correct.

The rejection of the claims under this section is based upon an interpretation of the claims that does not include all of the clearly defined claim limitations. As stated by the Examiner on page 4, lines 9-11, the invention is being construed as a method of monitoring reagents and their controls. However, in light of the explanation provided above with respect to the rejection under 35 U.S.C. §112, it is submitted that the claims contain specific steps and limitations that are neither disclosed nor suggested by any of the cited references. As previously argued, and as acknowledged by the Examiner, Fritchie et al do not disclose or suggest calculating a deviation between the results of analysis and the standard value when an accuracy management sample is newly analyzed by an automatic analyzing apparatus. The results of this analysis are used to verify that the analysis parameters used in the analysis are correct.

JP 5-288756 is cited in the present specification for the use of bar codes. JP 4-128657 discloses that a computer stores analytical results and parameters sent by

analytical devices as a set. Moreover, both JP 5-288756 and JP 4-128657 disclose taking an analysis parameter from the outside of an analysis device.

Applicant's wish to emphasize that a significant purpose of the present invention is to gather analyzed results for the accuracy management samples to the service center, to calculate a deviation between the analyzed results for the accuracy management sample and the standard value for the accuracy management sample, and to judge whether the analysis parameter which is used in the analysis is correct or not. Neither of these references disclose or suggest the above-mentioned features of the present invention.

Based upon the explanation provided above with respect to the rejection under 35 U.S.C. §112 and 35 U.S.C. §102, it is submitted that the pending claims set forth exact steps which can be followed by one of ordinary skill in the art and patentably define the present invention over the cited art.

Applicant's undersigned attorney respectfully requests an interview with the Examiner and will contact the Examiner to set an appropriate date and time.

Conclusion

In view of the foregoing, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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